CHAPTER 7
HOSPITAL PHARMACY LICENSES
[Prior to 2/10/88, see Pharmacy Examiners[620] Ch 12]

657—7.1(155A) General requirements. Hospital pharmacy means and includes a pharmacy: licensed by the board, located within any hospital, institution, or establishment which maintains and operates organized facilities for the diagnosis, care, and treatment of human illnesses to which persons may be admitted for overnight stay, and which meets all of the requirements of Iowa Code chapter 135B and the rules and regulations of the board. This chapter does not apply to a pharmacy located within such a facility for the purpose of serving noninstitutionalized patients. Such a pharmacy is a general pharmacy and shall be licensed pursuant to 657—Chapter 6. Pharmacists shall be responsible for any delegated act performed by supportive personnel under their supervision.

657—7.2(155A) Sanitation. Drugs shall be stored in a manner to protect their identity and integrity. A sink with hot and cold running water shall be available within the pharmacy and shall be maintained in a sanitary condition at all times.

657—7.3(155A) Reference library. References may be printed or computer-accessed. A reference library shall be maintained which includes, as a minimum, one reference from each of the following:

1. Current Iowa pharmacy laws, rules, and regulations.
2. A patient information reference, updated at least annually, such as:
- United States Pharmacopeia Dispensing Information, Volume II (Advice to the Patient);
- Facts and Comparisons Patient Drug Facts; or
- Leaflets which provide patient information in compliance with rule 657—8.20(155A).
3. A current reference on drug interactions, such as:
- Phillip D. Hansten's Drug Interactions; or
- Facts and Comparisons Drug Interactions.
4. A general information reference, updated at least annually, such as:
- Facts and Comparisons with current supplements;
- United States Pharmacopeia Dispensing Information, Volume I (Drug Information for the Healthcare Provider); or
- American Hospital Formulary Service with current supplements.
5. A current drug equivalency reference, including supplements, such as:
- Approved Drugs Products With Therapeutic Equivalence Evaluations;
- ABC - Approved Bioequivalency Codes; or
- USP DI, Volume III.
6. A current IV mixing guide such as:
- Betty Gahart's Intravenous Medications; or
- Trissel's Handbook on Injectable Drugs.
7. A current drug identification reference such as:
- Generex;
- Ident-a-Drug; or
- Other drug identification reference to enable identification of drugs brought into the facility by patients.
8. Basic antidote information or the telephone number of a poison control center.
9. Additional references as may be necessary for the pharmacist to adequately meet the needs of the patients served.

657—7.4(155A) Space and equipment requirements. There shall be adequate space, equipment, and supplies for the professional and administrative functions of the pharmacy.

1. The pharmacy shall be located in an area or areas that facilitate the provision of services to patients and shall be integrated with the facility's communication and transportation systems.
2. Space and equipment in an amount and type to provide secure, environmentally controlled storage of drugs shall be available. Equipment shall include a refrigeration unit. The temperature of

the refrigerator shall be maintained within a range compatible with the proper storage of drugs requiring refrigeration.

3. There shall be appropriate space and equipment suitable for the preparation of sterile products and other drug compounding and packaging operations. An appropriate IV preparation hood or room, certified annually pursuant to 657—8.30(126,155A), shall be accessible to personnel preparing IV solutions and other sterile products.

4. The pharmacist in charge shall ensure the availability of any other equipment necessary for the particular practice of pharmacy.

657—7.5(124,155A) Security. The following conditions must be met to ensure appropriate control over drugs and chemicals in the pharmacy:

7.5(1) *Access when pharmacist absent.* Policies and procedures shall be established which identify who will have access to the pharmacy when the pharmacist is absent from the premises and the procedures to be followed for obtaining drugs and chemicals during that absence. In determining the adequacy of security measures, the board will consider the factors outlined in rule 657—6.6(155A).

7.5(2) *Pharmacist in charge responsible.* The pharmacist in charge shall be responsible for implementing policies and procedures for the security of the hospital pharmacy, including provisions for adequate safeguards against theft or diversion of dangerous drugs, controlled substances, and records for such drugs.

657—7.6(155A) Pharmacist in charge. The pharmacy shall be directed by a professionally competent, legally qualified pharmacist.

7.6(1) *Qualifications—pharmacist in charge.* The pharmacist in charge shall be licensed by the board to practice pharmacy in Iowa. The pharmacist in charge shall be knowledgeable about hospital pharmacy practice and management.

7.6(2) *Support staff.* Sufficient supportive personnel, including technical, clerical, and secretarial staff, shall be available to minimize the use of pharmacists in nonjudgmental tasks. Appropriate supervisory controls for supportive personnel shall be maintained.

7.6(3) *Pharmacy personnel.* The pharmacist in charge shall employ an adequate number of qualified personnel commensurate with the size and scope of services provided by the facility.

a. All personnel shall possess the education and training needed for their responsibilities. Competence of all staff shall be maintained through relevant continuing education programs or other activities.

b. Personnel shall be selected and assigned solely on the basis of job-related qualifications and performance. The employment and discharge of pharmacy personnel shall be the responsibility of the pharmacist in charge. There shall be an established procedure, based on predetermined objectives, for orienting new personnel to the pharmacy and their respective positions. Procedures for the routine evaluation of pharmacy personnel performance shall be established.

c. Lines of authority and areas of responsibility within the pharmacy shall be clearly defined. Written position descriptions for all categories of pharmacy personnel shall be prepared and revised as necessary.

7.6(4) *Policies and procedures.* An operations manual governing all pharmacy functions shall be prepared. It shall be continually revised to reflect changes in procedures, organization, and other pharmacy functions. All pharmacy personnel shall be familiar with the contents of the manual.

7.6(5) *Pharmaceutical services.* There shall be an ongoing, systematic program for achieving performance improvement and ensuring the quality of pharmaceutical services.

a. The services of a pharmacist shall be available at all times. Where 24-hour operation of the pharmacy is not feasible, a pharmacist shall be available on an "on call" basis. The use of night cabinets and drug dispensing by nonpharmacists shall be minimized and eliminated wherever possible.

b. Some small facilities may not require, or be able to obtain, the services of a full-time pharmacist. However, it should be noted that the concepts, principles, and recommendations contained in this rule apply to all hospitals, regardless of size or type. Thus, the part-time pharmacist in charge has the same basic obligations and responsibilities as the full-time pharmacist in charge in the larger institution.

7.6(6) *Personnel histories.* Pursuant to the requirements of Iowa Code section 135C.33, the provisions of this subrule shall apply to any pharmacy employing any person to provide patient care services in a patient's home. For the purposes of this subrule, "employed by the pharmacy" shall include any individual who is paid, either by the pharmacy or by any other entity such as a corporate entity, a temporary agency, or an independent contractor, to provide treatment or services to any patient in the patient's home. Specifically excluded from the requirements of this subrule are individuals such as delivery persons or couriers who do not enter the patient's home for the purpose of instructing the patient or the patient's caregiver in the use or maintenance of the equipment, device, or medication being delivered, or who do not enter the patient's home for the purpose of setting up or servicing the equipment, device, or medication used to treat the patient in the patient's home.

a. The pharmacy shall ask the following question of each person seeking employment in a position which will provide in-home services: "Do you have a record of founded child or dependent adult abuse or have you ever been convicted of a crime, in this state or any other state?" The applicant shall also be informed that a criminal history and dependent adult abuse record check will be conducted. The applicant shall indicate, by signed acknowledgment, that the applicant has been informed that such record checks will be conducted.

b. Prior to the employment of any person to provide in-home services, the pharmacy shall submit a form specified by the department of public safety to the department of public safety and receive the results of a criminal history check and dependent adult abuse record check. The pharmacy may submit a form specified by the department of human services to the department of human services to request a child abuse history check.

c. A person who has a criminal record, founded dependent adult abuse report, or founded child abuse report shall not be employed by a pharmacy to provide in-home services unless the department of human services has evaluated the crime or founded abuse report and concluded that the crime or founded abuse does not merit prohibition from such employment.

d. The pharmacy shall keep copies of all record checks and evaluations.

657—7.7(155A) Training and utilization of pharmacy technicians. Hospital pharmacies utilizing pharmacy technicians shall develop, implement, and periodically review written policies and procedures for the training and utilization of pharmacy technicians. Pharmacy policies shall specify the frequency of review. Technician training shall be documented and maintained by the pharmacy for the duration of employment. Policies and procedures and documentation of technician training shall be available for inspection by the board or an agent of the board.

657—7.8(124,126,155A) Drug distribution and control. The pharmacist in charge shall be responsible for the procurement, distribution, and control of all drugs used within the institution. This responsibility extends to drugs and related services provided to ambulatory patients. Policies and procedures governing these functions shall be developed by the pharmacist in charge with input from other involved hospital staff such as physicians and nurses, from committees such as the pharmacy and therapeutics committee or its equivalent, and from any related patient care committee. In doing so, it is essential that the pharmacist in charge or designee routinely be available to or on all patient care areas, establish rapport with the personnel, and become familiar with and contribute to medical and nursing procedures relating to drugs.

7.8(1) *Drug formulary.* The pharmacist in charge shall maintain a current formulary of drug products approved for use in the institution and shall be responsible for specifications for those drug products and for selecting their source of supply.

7.8(2) *Investigational drugs.* The pharmacy shall be responsible for establishing policies and procedures controlling the use of investigational drugs if used in the institution.

a. A pharmacist shall be a member of the institutional review board.

b. The pharmacy shall be responsible, in cooperation with the principal investigator, for providing information about investigational drugs used in the institution.

c. If applicable, the pharmacist shall conduct, participate in, and support medical and pharmaceutical research appropriate to the goals, objectives, and resources of the pharmacy and the institution.

7.8(3) *Disaster services.* There shall be a procedure for providing drugs and pharmaceutical services in the event of a disaster.

7.8(4) *Samples.* The use of drug samples within the institution shall be eliminated to the extent possible. However, if the use of drug samples is permitted, they shall be controlled and distributed through the pharmacy or through a process developed in cooperation with the pharmacy and the institution's appropriate patient care committee, subject to oversight by the pharmacy.

7.8(5) *Medication orders.* The pharmacist shall review an authorized prescriber's original order, or a direct copy, prior to dispensing any drug except for emergency use. There shall be no transcribing of medication orders by nursing or clerical staffs except for their own records. Hospitalwide and pharmacy stand-alone computer systems shall be secure against unauthorized entry. All orders shall use only standard approved abbreviations and chemical symbols. All systems shall provide for review and verification of the prescriber's original order before the drug is dispensed.

7.8(6) *Drug distribution.* The pharmacist shall institute the control procedures needed to ensure that patients receive the correct drugs at the proper times.

a. In the interest of patient safety, all drugs dispensed by the pharmacist for administration to patients shall be in single unit packages if practicable. Thus, the need for nurses to manipulate drugs prior to their administration should be minimized.

b. Where applicable, pharmacy personnel shall prepare all sterile products including chemotherapy injections, continuous and intermittent intravenous preparations, and irrigation solutions, except in emergencies.

c. When feasible, the pharmacist shall prepare those drug formulations, strengths, dosage forms, and packages that are not available commercially but which are useful in the care of patients. Adequate quality assurance procedures shall be developed for these operations.

7.8(7) *Hazardous drugs and chemicals.* The pharmacist, in cooperation with other hospital staff, shall establish policies and procedures for handling drugs and chemicals that are known occupational hazards. The procedures shall maintain the integrity of the drug or chemical and protect the hospital personnel.

7.8(8) *Emergency drug supplies and floor stock.* Supplies of drugs for use in medical emergencies shall be immediately available at each nursing unit or service area as specified in policies and procedures. Stocks of drugs shall be as limited as possible. Authorized stocks shall be periodically reviewed in a multidisciplinary manner. All drug storage areas within the hospital shall be routinely inspected to ensure that no outdated or unusable items are present and that all stock items are properly labeled and stored.

7.8(9) *Product recall.* There shall be a system for removing from use any drugs subjected to a product recall.

7.8(10) *Stop order.* A written stop-order policy or other system shall be established to ensure that drug orders are not inappropriately continued.

7.8(11) *Drugs brought into the institution.* Policies and procedures shall be established for the identification of medications brought into the institution for use by patients.

657—7.9(124,155A) Drug information. The pharmacy is responsible for providing the institution's staff and patients with accurate, comprehensive information about drugs and their use and shall serve as its center for drug information.

7.9(1) *Staff education.* The pharmacist shall keep the institution's staff well-informed about the drugs used in the institution and their various dosage forms and packagings.

7.9(2) *Patient education.* The pharmacist shall help ensure that all patients are given adequate information about the drugs they receive. This is particularly important for ambulatory, home care, and discharge patients. These patient education activities shall be coordinated with the nursing and medical staffs and patient education department, if any.

657—7.10(124,155A) Ensuring rational drug therapy. An important aspect of pharmaceutical services is that of maximizing rational drug use. In this regard, the pharmacist, in concert with the medical staff, shall develop policies and procedures for ensuring the quality of drug therapy.

7.10(1) *Patient profile.* Sufficient patient information shall be collected, maintained, and reviewed by the pharmacist to ensure meaningful and effective participation in patient care. This requires that a medication profile be maintained for all inpatients and for those ambulatory patients routinely receiving care at the hospital. A pharmacist-conducted medication history from patients may be useful in this regard.

a. Appropriate clinical information about patients shall be available and accessible to the pharmacist for use in daily practice activities.

b. The pharmacist shall review each patient's drug regimen on a concurrent basis and directly communicate any suggested changes to the prescriber.

7.10(2) *Adverse drug events.* The pharmacist, in cooperation with the appropriate patient care committee, shall develop a mechanism for the reporting and review, by the committee or other appropriate medical group, of adverse drug events.

657—7.11(126,155A) Unit dose dispensing systems.

7.11(1) *Definitions.* For the purposes of this rule, the following definitions shall apply:

"Single unit package" is a package which contains one discrete pharmaceutical dosage form.

"Unit dose dispensing systems" are those drug distribution systems determined by the board to be pharmacy-based and which involve single unit, unit dose, or unit of issue packaging in a manner which helps reduce or remove traditional drug stocks from patient care areas and enables the selection and distribution of drugs to be pharmacy-based and controlled.

"Unit dose package" is a package which contains that particular dose of a drug ordered for the patient for one administration time. A unit dose package is not always a single unit package.

"Unit of issue package" is a package which provides multiple units/doses attached to each other but separated in a card or specifically designed container.

7.11(2) *Packaging requirements.* Packaging for all nonsterile drugs stored and dispensed in single unit, unit dose, or unit of issue packages shall:

a. Preserve and protect the identity and integrity of the drug from the point of packaging to the point of patient administration.

b. When packaged by the manufacturer or distributor, be in accordance with federal Food and Drug Administration (FDA) requirements.

c. When in single unit and unit dose packages prepackaged by the pharmacy for use beyond 24 hours, be in accordance with 657—subrule 8.3(1).

d. When in containers used for packaging, be clean and free of extraneous matter when the dosage unit(s) is placed into the package.

7.11(3) *Labeling requirements.*

a. Labeling for single unit or unit dose packaging shall comply with the following:

(1) Doses packaged by the manufacturer or distributor shall be properly labeled according to federal Food and Drug Administration (FDA) requirements.

(2) Doses packaged by the pharmacy shall be properly labeled according to 657—subrule 8.3(2) if used beyond a 24-hour period.

b. Labeling for unit of issue packages shall contain the following information:

(1) Name, strength, and expiration date of drug when the packages are utilized for floor stock in an institutional setting.

(2) Name and room or bed number of patient, name of prescribing practitioner, name and strength of drug, directions for use, and name and address of the dispensing pharmacy, when the packages are utilized for patients in an institutional setting. Room or bed number, the name of prescribing practitioner, and the name and address of the dispensing pharmacy are not required if this information appears on a medication administration record used by the institution.

(3) Unit of issue packages dispensed to patients on an out-patient basis or in a noninstitutional setting shall be considered prescription containers and shall be labeled in accordance with 657—subrule 8.14(1).

c. If a pharmacist selects a generically equivalent drug product for a brand name drug product prescribed by a practitioner, the label must identify the generic drug and may identify the brand name drug for which the selection is made. The dual identification allowed under this paragraph must take the form of the following statement on the label: "(generic name) Generic for (brand name product)".

7.11(4) *General procedures.* The following will apply when a unit dose dispensing system is employed:

a. The pharmacist shall be responsible for determining the classification for containers set by USP Standard 671 used by the pharmacy to repackage nonsterile drugs into single unit, unit dose, or unit of issue packaging. This classification shall be used to determine maximal expiration dating for repackaging set forth in subrule 7.11(5).

b. Established written policies and procedures shall be available in the pharmacy for inspection by the board or its agents which:

(1) Specify the categories of drugs or drug dosage forms which will or will not be dispensed under the particular unit dispensing system employed.

(2) Specify the pharmacy's recall policy for drugs returned upon a particular manufacturer's or FDA recall.

c. Those drugs not dispensed under a unit dose dispensing system shall be dispensed in accordance with the packaging requirements of the federal Food and Drug Administration (FDA) and labeling requirements of 657—subrule 8.14(1).

7.11(5) *Expiration dating.* Expiration dating for nonsterile drugs repackaged by the pharmacy into single unit, unit dose, or unit of issue packages shall meet the following conditions:

a. Not exceed 90 days from the date of repackaging except as provided in paragraph 7.11(5)*"c."*

b. Not exceed the manufacturer's original expiration date.

c. May exceed 90 days from the date of repackaging provided that each of the following conditions is met:

(1) The container is classified according to USP Standard 671 as being Class A or Class B for oral solid dosage forms or is a tight container for liquid dosage forms.

(2) The container is light-resistant when the manufacturer has labeled the product "sensitive to light."

(3) The expiration date is not greater than 12 months.

d. Drugs or dosage forms having known stability problems are assigned an expiration date of less than 90 days or are not repackaged as determined by policies developed by the pharmacy.

7.11(6) *Return of drugs.* Drugs dispensed in single unit, unit dose, or unit of issue packaging in compliance with subrules 7.11(1) to 7.11(5) may be returned to the pharmacy stock and reissued provided that:

a. The expiration dating information is retrievable and identifiable.

b. Drugs returned from unit of issue packaging are kept separate according to manufacturer's lot number and the pharmacy's repackaged expiration date unless the pharmacy's recall policy states that all lots of a drug will be returned upon recall. In this instance, drugs returned to stock shall be kept separate according to the pharmacy's repackaged expiration date as determined in subrule 7.11(5).

c. The drugs were stored under proper storage conditions.

d. The drugs are returned to the pharmacy in the original packaging as when dispensed.

e. The pharmacy includes in its written policies and procedures the manner in which it will record or identify controlled substances returned.

This rule is intended to implement Iowa Code sections 124.301, 126.10, 155A.13, and 155A.28.

657—7.12(124,126,155A) Drugs dispensed to patients as a result of an emergency room visit. In those facilities with 24-hour pharmacy services, any drugs dispensed to an outpatient, including emergency department patients, may be dispensed only by a pharmacist or practitioner. In those facilities without 24-hour pharmacy services, or those facilities without outpatient pharmacy services, or when outpatient pharmacy services are not available, the following procedures shall be observed in dispensing drugs:

7.12(1) *Patients examined in emergency room.* Drugs may be dispensed only to patients who have been examined in the emergency room.

7.12(2) *Accountability.* Drugs may be dispensed only in accordance with the system of control and accountability for drugs administered or dispensed from the emergency room.

a. Such system shall be developed and supervised by the pharmacist in charge and the facility's emergency department committee, or a similar group or person responsible for policy in that department.

b. The system shall consist of drugs of the nature and type to meet the immediate needs of emergency room patients.

c. Controlled substances maintained in the emergency room are kept for use by, or at the direction of, prescribers in the emergency room. In order to receive controlled drugs, a patient must be examined by a prescriber in the emergency room where the need for a controlled substance must be determined. It is not permissible under state and federal requirements for a prescriber to see a patient outside of the emergency room setting, or talk to the patient on the telephone, and then proceed to call the emergency room and order the administration of a stocked controlled substance upon the patient's arrival at the emergency room.

d. The pharmacist in charge is responsible for maintaining accurate records of dispensing of drugs from the emergency room.

7.12(3) *Prepackaging.* Drugs dispensed in greater than a 24-hour supply may be dispensed only in prepackaged quantities not to exceed a 72-hour supply or the minimum prepackaged quantity in suitable containers and appropriately labeled as required in subrule 7.12(4), including necessary auxiliary labels.

7.12(4) *Labeling.* At the time of delivery of the medication, the practitioner shall appropriately complete the label, such that the dispensing container bears a label with at least the following information:

1. Name and address of the hospital;
2. Date dispensed;
3. Name of prescriber;
4. Name of patient;
5. Directions for use;
6. Name and strength of drug.

7.12(5) *Delivery of medication to patient.* The practitioner, or a licensed nurse under the supervision of the practitioner, shall give the appropriately labeled, prepackaged medication to the patient and explain the correct use of the drug.

7.12(6) *Verification of dispensing record.* Rescinded IAB 1/1/97, effective 2/5/97.

657—7.13(124,155A) Records. Every inventory or other record required to be kept under this chapter or under Iowa Code chapters 124 and 155A shall be kept by the pharmacy and be available for inspection and copying by the board or its representative for at least two years from the date of such inventory or record except as otherwise required in this rule.

7.13(1) *Medication order information.* Each original medication order contained in inpatient records shall bear the following information:

a. Patient name and identification number;

b. Drug name, strength, and dosage form;

c. Directions for use;

d. Date;

e. Practitioner's signature or that of the practitioner's authorized agent. Any order signed by an authorized agent shall be cosigned by the practitioner within 72 hours.

7.13(2) *Medication order maintained.* The original medication order shall be maintained with the medication administration record in the medical records of the patient following discharge.

7.13(3) *Documentation of drug administration.* Each dose of medication administered shall be properly recorded in the patient's medical record.

7.13(4) *Controlled substances records.* Controlled substances records shall be maintained as follows:

a. All records for controlled substances shall be maintained in a readily retrievable manner.

b. Controlled substances records shall be maintained in a manner to establish receipt and distribution of all controlled substances.

c. Schedule II controlled substances records shall be maintained separately from records of controlled substances in Schedules III, IV, and V, and all other records.

d. Distribution records for non-patient-specific, floor-stocked controlled substances shall bear the following information:

(1) Patient's name;

(2) Prescriber who ordered drug;

(3) Name of drug, dosage form, and strength;

(4) Time and date of administration to patient and quantity administered;

(5) Signature or unique electronic signature of individual administering controlled substance;

(6) Returns to the pharmacy;

(7) Waste, which is required to be witnessed and cosigned by another licensed health professional.

7.13(5) *Other pharmacy records.* Other records to be maintained by a pharmacy include:

a. Copy 3 of DEA order Form 222 which has been properly dated, initialed, and filed, and all copies of each unaccepted or defective order form and any attached statements or other documents.

b. Supplier's invoices of prescription drugs and controlled substances upon which is clearly recorded the actual date of receipt of the controlled substances by the pharmacist or other responsible individual.

c. Suppliers' credit memos for controlled substances and prescription drugs.

d. Biennial inventory of controlled substances required by the Drug Enforcement Administration that shall be maintained for a minimum of four years from the date of the inventory.

e. Drug Enforcement Administration reports of theft or significant loss of controlled substances.

f. Reports of surrender, destruction, or disposition of controlled substances.

g. Schedule V nonprescription register book, if applicable.

h. If a pharmacy distributes controlled substances to another pharmacy or a practitioner, the following records shall be maintained by the distributing pharmacy:

(1) If for Schedule III, IV, or V controlled substances, invoices showing the actual date of distribution; the name, strength, and quantity of controlled substances distributed; the name, address, and DEA registration number of the distributing pharmacy; and the name, address, and DEA registration number of the pharmacy or practitioner to whom the controlled substances are distributed.

(2) If for Schedule I or II controlled substances, copy 1 of DEA order Form 222, furnished by the pharmacy or practitioner to whom the controlled substances are distributed, showing the quantity of controlled substances distributed and the actual date of distribution.

These rules are intended to implement Iowa Code sections 124.301, 124.303, 124.306 to 124.308, 126.10, 155A.13, 155A.28, 155A.31 and 155A.32.

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